groups are described here for children (proxy EQ-5D and KS) and parents (EQ-5D). Optimal compliance: proxy EQ-5D 0.8257, KS 47.5152, EQ-5D 0.8331. Suboptimal compliance: proxy EQ-5D 0.7321, KS 42.7671, EQ-5D 0.8050. Medication use stopped: proxy EQ-5D 0.7635, KS 42.5969, EQ-5D 0.8169. Remission after medication use: proxy EQ-5D 0.8518, KS 45.8929, EQ-5D 0.8220. Naïve to medication: proxy EQ-5D 0.7719, KS 43.3744, EQ-5D 0.7899. **CONCLUSIONS:** Children with a good compliance to medication and naïve children have a better QoL compared to non-compliant children and children who stopped treatment (non-remission). The QoL of children in remission is better than the QoL of children using medication. QoL of parents follows a similar pattern.

PMH47

VALIDITY OF THE Q10 QUESTIONNAIRE FOR DIAGNOSIS OF WEARING-OFF PHENOMENA IN PARKINSON'S DISEASE: A Q10 STUDY

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OBJECTIVES: To test the characteristics of a QUICK Questionnaire-Short version (Q10) as diagnostic instrument for wearing-off phenomenon (WO) in Parkinson's disease (PD) patients. **METHODS:** Observational, cross-sectional, multicenter, and national study developed in clinical practice. The study was developed in two consecutive phases: I, to determine the sensitivity and specificity of Q10; and II: to assess the usefulness (investigators) and the ability and ease of use (patients) of Q10 questionnaire. Furthermore, the prevalence of WO among PD patients consecutively attending the specialist was also assessed (phase II). Patients ≥30 years old at the onset of the disease with ≤5 years from diagnosis and under treatment were selected. **RESULTS:** In phase I, 162 patients were included, 67.4±9.7 years old, 53.8% males, and 3.1±1.4 years from diagnosis. Most of them (85%) were in Hoehn-Yahr stage 2-3. WO was presented in 64.8% (33.3% mild; 31.5% moderate/severe). Q10 was completed in 6.6±4.9 minutes. With two positive responses the Q10 showed good sensitivity (90%) and moderate specificity (70%) and with 3 positive responses both values reached an arbitrarily hypothesized 75% threshold (sensitivity: 81%; specificity: 75%). The mean usefulness Q10 score was good [7.3 (1.6), scale 1-10]. In phase II, most patients considered Q10: easy to understand (80.6%), reflect their present situations (78.8%), and useful to communicate discomfort to the doctor (80.6%). The prevalence of WO among the total PD patients attending to the neurologist was of 59.0%, higher in males (64.9%), Hoehn-Yahr staging (80%, 3-4 stage) and in patients with more time of PD evolution (71.9%). **CONCLUSIONS:** The Q10 is a useful instrument for screening and diagnosis of WO, showing good sensitivity and specificity, as well as, good usefulness, ability and ease to use. Almost two out of three PD patients attending to the neurologist presented WO.

PMH48

THE SPANISH VERSION OF THE CLINICALLY USEFUL DEPRESSION OUTCOME SCALE: A VALID INSTRUMENT TO EVALUATE DEPRESSIVE SYMPTOMS IN PRIMARY CARE

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OBJECTIVES: Develop a cross-cultural adaptation, English to Spanish, of the Clinically Useful Depression Outcome Scale (CUDOS): a validated instrument to assess depressive symptoms in patients with major depressive disorder (MDD). **METHODS:** CUDOS is a brief self-administered scale with 18 items assessing all of the DSM-IV inclusion criteria for MDD, psychosocial impairment and patients' quality of life. Three independent translators (2 Spanish and 1 English) performed forward-backward translations of the original scale. Draft version was reviewed by an expert panel (4 general practitioners, 1 psychiatrist, and 2 psychologists) and tested in 19 adult patients with MDD. Regarding experts' and patients' responses, comprehension and importance (C/I) of each item were evaluated using a Likert scale ranging from 0 (lowest level of C/I) to 4 (highest level of C/I). Furthermore, feasibility, ceiling and floor effects and reliability were preliminary analyzed. **RESULTS:** According to experts' criteria, mean C/I values of items were over 2 points (comprehension mean range: 3.25-4 & importance mean range: 2.5-4). Regarding patients' responses, acceptable mean values in comprehension (range: 2.26-3.37) were obtained. However, 4 items were modified to improve comprehension: loss of interest in usual activities, psychomotor retardation, indecisiveness and hopelessness Patients reported low importance scores in items related to thoughts of death (mean= 1.42), suicidal ideation (mean= 1.26), guilt (mean= 1.79), hypersomnia (mean= 1.37) and insomnia (mean= 1.78). Missing data was only found in 2 patients. Internal consistency was high (Cronbach $\alpha = .886$), Neither item ceiling nor floor effects were observed and patients perceiving a moderate to severe psychosocial impairment obtained higher CUDOS scores –indicating a higher impact- than those with mild or null impairment (Mann-Whitney U=9.500; p=.019). Finally, the Spanish version of the CUDOS was reached by consensus. **CONCLUSIONS:** The original CUDOS instrument was culturally adapted into Spanish. Psychometric analyses are needed to validate this measure in Spain.

PMH49

DEVELOPMENT AND CONTENT VALIDITY OF A PATIENT REPORTED OUTCOMES MEASURE TO ASSESS SYMPTOMS OF MAJOR DEPRESSIVE DISORDER (MDD)

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OBJECTIVES: FDA guidance on the use of Patient Reported Outcomes (PRO) for product labeling claims emphasizes the importance of documented evidence of patient input in PRO instrument development. A review of existing PROs used in Major Depressive Disorder (MDD) suggested the need to conduct qualitative research with patients with MDD to better understand their experience of MDD and develop an evaluative instrument with content validity. The aim of this study was to develop such a measure. **METHODS:** Ten MDD severity-specific focus groups (n=3-4 patients per group; total n=38) with adult patients between the ages of 18 and 65 having a clinician-confirmed diagnosis of MDD and varying in severity levels as defined by the DSM-IV TR criteria were conducted in January 2009. Grounded theory data collection and analysis methods were used including an open-ended discussion guide, an iteratively developed coding scheme, and the comparison of coded segments of patients' quotes to identify the patient experienced signs and symptoms of MDD. Saturation of concepts, where no new relevant information emerges in later interviews, was assessed. A new PRO instrument for MDD was developed; cognitive interviews (n=20) were conducted to test its content validity in terms of item relevance and comprehension, comprehensiveness, instructions, recall period and response categories. **RESULTS:** Thirty-five unique concepts falling into the following 6 domains: emotional symptoms; ideation symptoms; neuro-vegetative or somatic symptoms; physical impact; social impact; and cognitive impact were elicited. Concept saturation was achieved for each of the symptom concepts across severity levels. The MDD PRO instrument includes 15 daily and 21 weekly items. Cognitive interviews supported its content validity. Items were revised, deleted, or moved from daily to weekly assessment based on cognitive interview results **CONCLUSIONS:** Rigorous qualitative research resulted in the development of a PRO measure for MDD with supported content validity; its psychometric properties and responsiveness requires assessment.

PMH50

DIFFERENCES BETWEEN OPIOID DEPENDENT PATIENTS IN ITALY AND GERMANY RECEIVING SUBSTITUTION THERAPY

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OBJECTIVES: Substitution therapy is commonly used across the world for the treatment of opioid dependence (OD), yet little evidence exists examining country-specific differences between acceptance and effectiveness of this treatment. The purpose of this study was to examine differences between patient demographics, treatment accessibility, and attitudes toward substitution therapy among OD patients in Germany and Italy. **METHODS:** A telephonic survey, initiated by the Italian Federation of Operators of Dependences Departments and Services, examining substitution therapy was administered to OD patients across two countries: Germany (n=200) and Italy (n=378). The survey assessed experiences prior to and during substitution therapy. **RESULTS:** Italian patients reported being in better physical and mental health than German patients (p's < 0.001); were more likely to get information about substitution therapy from family members than German patients (8.9% vs. 3.2%, $\chi 2 = 5.22$; $p < 0.05$); and were more likely to report that it was either very easy or fairly easy to find a doctor from whom they could receive substitution treatment than German patients (89.9% vs. 68.7%, $\chi 2 = 40.35$; $p < 0.001$). In contrast, German patients were more likely to get information from other drug users (63.9% vs. 47.7%, $\chi 2 = 10.72$; $p < 0.01$) or their family physicians (14.6% vs. 4.3%, $\chi 2 = 14.59$; $p < 0.0001$), and were also more likely than Italian patients to misuse their substitution drug by either snorting (11.5% vs. 3.2%, $\chi 2 = 15.94$; $p < 0.0001$) or injecting it (18.5% vs. 11.1%, $\chi 2 = 6.05$; $p < 0.05$). **CONCLUSIONS:** The present results highlight key differences in patient attitudes and experiences regarding substitution therapy. Differences in social and institutional attitudes, in addition to cultural norms and health care policies, may explain the present findings, which demonstrate the complexity of the OD population.

PMH51

MEASURING RELAPSE AFTER SUBSTANCE ABUSE TREATMENT: A PROPORTIONAL HAZARD APPROACH

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OBJECTIVES: This research uses Cox regression to analyze relapse patterns of adults treated for substance use disorder (SUD). The objective is to evaluate the role psychosocial, treatment and environmental characteristics play in the relapse process. While relapse is a much-studied phenomenon, there is no research describing in detail how the risk of relapse changes over time (especially in the months immediately following primary treatment) given known protective factors. Since SUD is a chronic relapsing disorder, it is important to understand ways treatment gains can be maintained. **METHODS:** Subjects are 408 adults discharged between 2000-2009 from an ASAM-defined Level 1.A primary inpatient treatment program. Data were collected via a 215-item questionnaire as part of the treatment program's annual outcomes evaluation. The sampling frame was people who successfully completed treatment and who gave consent. The response rate was 56 percent. The researchers obtained the treatment records of each person completing the questionnaire and matched the treatment outcomes from the questionnaire to treatment and sociodemographic variables present in the treatment records. A comprehensive data set was created from these two sources. Data were analyzed using Cox proportional hazard regression. **RESULTS:** Statistically significant covariates include: home environment variables (those with supportive people at home are 3.17 times less likely to relapse; those with supportive spouses are 4.91 times less likely to relapse) and support group variables (those attending self-help meetings